Left Ventricular Bypass Pump for Cardiac Assistance

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Clinical Experience

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A gas-energized, synchronized, hemispherical pump, of Dacron®-reinforced Silastic®, has been used effectively to relieve the strain on the failing left ventricle during the early recuperative period after open heart surgery. Since 1963, when an early version was implanted in a patient, numerous improvements have been made, among the most important of which has been use of Dacron velour lining to minimize trauma to the blood.

Two illustrative cases demonstrate the effectiveness of the pump during relatively sustained use: until the fourth postoperative day in a young girl with long-standing rheumatic heart disease, severe mitral insufficiency and cardiac failure; and until the tenth postoperative day in a woman with severe aortic insufficiency and mitral stenosis who required replacement of both valves. Both patients, critically ill before operation, recovered completely. Experimental and clinical experience indicates that the pump, by immediately reducing left atrial pressure and therefore left ventricular end-diastolic pressure, interrupts the vicious cycle of complex metabolic changes consequent to the hemodynamic disturbances associated with cardiac failure.

The need for thoracotomy and the prohibitive cost, however, obviate broad clinical application of the pump. Development of a mechanical device for long-term support or for total cardiac replacement awaits the resolution of several critical problems, including a nontraumatic blood interface, improved control mechanism and portable power source.

For more than a decade, the development of a mechanical pump to assist or replace heart function has engaged the interest of our research team as a means of maintaining circulation in patients with irreversible cardiac failure. Our early research in this field proved the feasibility of duplicating the pumping action of the heart by a mechanical substitute, but it was obvious that the collaboration of biologic and physical scientists was needed. Accordingly, in 1963 the Biomedical Engineering Laboratory of Rice University joined our Surgical Research Laboratories at Baylor in this endeavor. Our artificial heart team discovered that a number of problems encountered in our initial attempts to devise a means of total cardiac replacement[1,2] would require long-term investigation, and we therefore turned our immediate attention to the development of a pump for support of the failing left ventricle,[3-7] a goal that might be more readily achieved and that might benefit a large number of patients who required such assistance.

The left ventricular bypass pump which resulted from this re-

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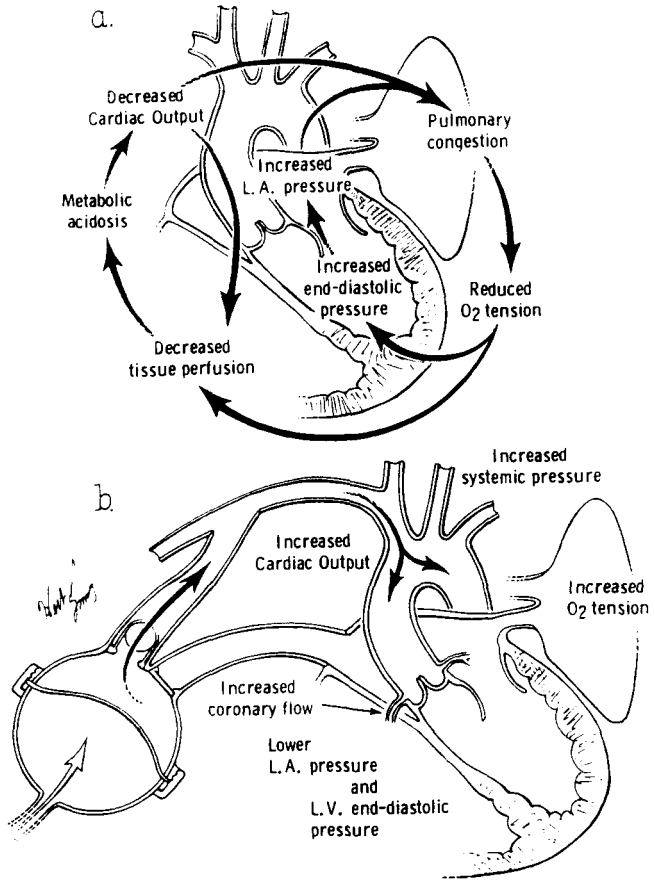

Figure 1. Function of left ventricular bypass pump. **a,** vicious cycle produced by a series of complex metabolic disturbances consequent to hemodynamic abnormalities caused by left ventricular failure. **b,** the left ventricular bypass pump interrupts this cycle by reducing left atrial (L.A.) pressure and therefore left ventricular (L.V.) end-diastolic pressure. The strain on the left ventricle is mitigated, pulmonary congestion is relieved and arterial oxygen tension is improved. With increased coronary perfusion, cardiac output improves and recuperation of the myocardium is thus enhanced.

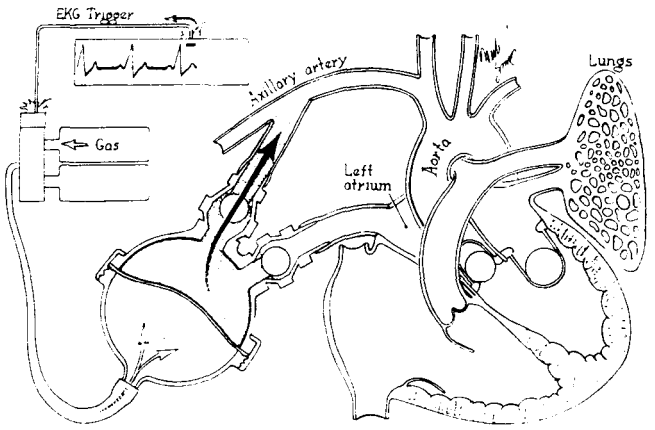

Figure 2. Method of connection of left ventricular bypass pump to left atrium and axillary artery after valvular replacement. Power may be synchronized with the electrocardiogram to pump blood during diastole, when the aortic valve is closed, or it may be regulated manually. Stroke volume and rate may be regulated to determine output.

search was first used for about 2 years in several hundred animals for which it proved safe and effective.[4-8] In 1966, after experimental observations provided satisfactory evidence that this pump could duplicate the function of the left ventricle for several weeks or longer without significant hematologic changes, the pump was applied effectively in a small series of patients who were critically ill with heart failure resulting from valvular heart disease. This success, along with the performance of the first human cardiac transplantation in 1967, prompted renewed vigorous efforts to develop a biventricular pump.[9] Our current model of the biventricular orthotopic cardiac prosthesis is a direct outgrowth of our research to perfect the left ventricular bypass pump.

Function of Left Ventricular Bypass Pump

The goal in developing a left ventricular bypass pump is to relieve strain on the failing heart during the critical recuperative period after cardiac damage. Ineffective emptying of a failing left ventricle during systole decreases cardiac output and lowers systemic pressure. The increase in left ventricular end-diastolic pressure inhibits filling from the left atrium, and the resulting rise in left atrial pressure increases pulmonary venous pressure and causes pulmonary congestion. The complex metabolic changes consequent to these hemodynamic disturbances, if unattended, produce a vicious cycle that leads to rapid deterioration of the patient's condition (Fig. 1a). The reduction in arterial oxygen tension caused by the pulmonary congestion further inhibits tissue perfusion, which has already been impaired by the low cardiac output. The resulting severe metabolic acidosis further restricts cardiac function and, if this series of events is not reversed, vasopressor-resistant hypotension, hypoxemia, arrhythmia and death ensue.

Use of the left ventricular bypass pump interrupts this cycle by immediately lowering left atrial pressure and, therefore, left ventricular end-diastolic pressure (Fig. 1b). Strain on the failing left ventricular myocardium is reduced, and pulmonary congestion is relieved, with improvement in arterial oxygen tension. The resultant prompt increase in cardiac output and in coronary flow of well-oxygenated blood to the myocardium enhances recuperability of the myocardium and left ventricular function.

Description of the Pump

The left ventricular bypass pump is a gas-energized synchronized pump of hemispherical design made of Dacron-reinforced Silastic, with a molded diaphragm separating the gas chamber from the blood chamber. Pressurized CO_2 pulsed into the gas chamber collapses

the central lumen or blood chamber and thereby empties it. A Teflon® bellows driven by an electric motor constitutes the external energizing and controlling system. The pump may be controlled manually or by an electrocardiographic triggering mechanism (Fig. 2). The speed of the motor is controlled by phase-variable firing of silicon-controlled rectifiers, and a dynamic braking circuit brings the motor to a complete stop at the end of each stroke. Synchronization is maintained by initiation of a stroke from each electrocardiographic signal, every other signal or every third signal. This override circuit also insures continuous operation, not necessarily synchronized, in case the electrocardiographic rate should rise sharply or be interrupted. Stroke and volume may be regulated to determine output. The transistorized control system has a minimum of switch and relay contacts. An independent power supply operates the system without synchronization, and the entire system can become a portable unit for as long as 1 hour by use of a battery-powered converter.

The pump lies completely outside the body (Fig. 3). One connecting tube is inserted, through an intercostal incision, into the left atrium and the other, through a small incision, into a systemic artery, such as the right axillary artery, which is readily accessible and requires insertion of only 1 tube into the chest. When the pump is no longer needed, its removal is relatively simple and consists essentially in dividing the connecting tubes just beneath the skin, under local anesthesia, and oversewing the proximal ends and then suture-closing the subcutaneous tissue and skin overlying the closed ends of the tubes.

An early version was implanted in a patient for the first time in 1963; it was attached to the left atrium and to the descending portion of the aorta.[8] We had not yet begun to line the pump with Dacron velour, however, and after 48 hours of pumping, thrombi and emboli began to form. We have since circumvented this problem to some extent and are continually modifying the design of these pumps to improve their efficacy and to make them simulate more closely the pumping function of the natural ventricle.

The interface: Although a number of problems remain to be solved before a mechanical substitute for the heart can be used safely and effectively for prolonged periods, we have now defined and classified the major obstacles. The most important of these is the *interface*, or contact surface of the blood when it moves from its normal habitat within the heart and blood vessels to the artificial environment of the mechanical pump. When the blood leaves its contact with normal intimal and endocardial surfaces and flows over a foreign surface of any kind, it undergoes abnormal changes, and the longer this contact continues, the more severe become the changes. Solutions to the other problems (control mechanism, biomaterials and power or energy source) cannot be properly applied until a satisfactory lining is found, and so we have concentrated particularly on improving the blood interface.

Our previous experience with artificial arteries led to the development of a surface similar to the normal intima of arteries. In Figure 4, to the right side of the suture line, is a Dacron tube that has been functioning for about 2 years after implantation. On the left side is a Teflon tube that has been in place for

Figure 3. Left ventricular bypass pump shown in place in a patient (Case 3) who had had valvular replacement. On the ninth day after operation and the ninth day of use of the left ventricular bypass pump, the condition of this patient (whose roentgenograms are shown in Figure 10A) continued to improve. The outflow of the left ventricular bypass pump was therefore decreased to 350 ml/min, and the patient was able to get out of bed.

the same amount of time. The surface of the Dacron prosthesis is completely covered with glistening material, or tissue, that adheres closely to it, whereas the Teflon prosthesis is covered with a fibrinous, somewhat clotted material that does not adhere to the fabric. Inspection of the Dacron material in many patients 5 to 10 years after implantation shows a glistening, pale-white surface that closely resembles intima.[10] Its thinness, on cross section, indicates that it does not thicken with time. Histologic section shows the Dacron fibers to be completely surrounded by newly formed fibrous tissue, which makes a smooth intimal surface completely adherent to the Dacron fibers, in what corresponds to the subintimal region. Indeed, in some instances small atheromas have been observed on this neointimal surface after several years.

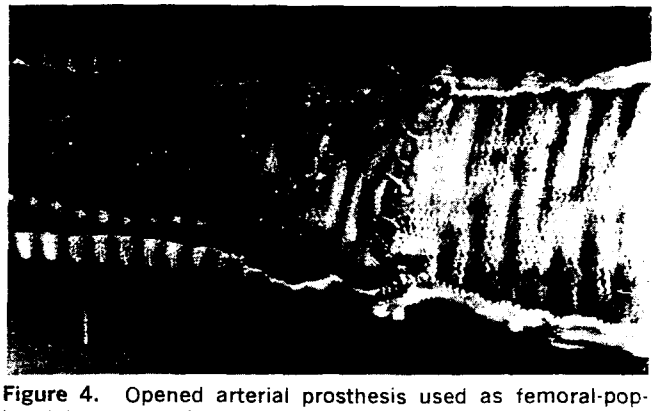

Figure 4. Opened arterial prosthesis used as femoral-popliteal bypass graft removed at operation 2 years after implantation. **Left,** Teflon portion of the prosthesis shows fibrinous clotted material that is not adherent to the fabric. **Right,** Dacron prosthesis, which had been functioning for some time, is completely covered with smooth, glistening adherent material that closely simulates natural intima.

This experience acquired from use of artificial arteries suggested an interface of Dacron for our mechanical pump. Unlike the Dacron artery, however, which remained fixed after implantation, the mechanical pump required a mobile structure in which the repeated to and fro motion of the diaphragm produced some breakage of the fibrinous elements adherent to it. For this reason, we began using Dacron velour and found that the fibrinous material deposited by the blood becomes enmeshed in the loops of the velour surface to create a new surface in which the fibrinous elements adhere firmly to the Dacron velour fabric (Fig. 5). The fibrinous material eventually becomes well organized, and the resulting surface appears compatible with blood.

Clinical Experience

The need for a temporary assistive device such as the left ventricular bypass pump is evident to every cardiologist who sees patients with myocardial infarction or coronory arterial disease dying from pump failure because of inability to provide adequate circulatory assistance to keep the patient alive until effective cardiac output can be restored. Cardiac surgeons too recognize this need when they see a patient dying on the operating table from cardiac failure, after surgical correction of the cardiac lesion, because the heart cannot maintain the circulation once extracorporeal bypass is discontinued. Experience has repeatedly shown that if extracorporeal circulation is discontinued abruptly, the heart sometimes fails, but that if its use is resumed for an hour or more, the heart may then take over this function satisfactorily. However we also observed that in some instances extracorporeal support was needed for days or weeks—longer intervals than could be provided by the heart-lung machine. The left ventricular bypass pump is designed to provide more protracted support of this kind. These observations may be exemplified by the following cases.

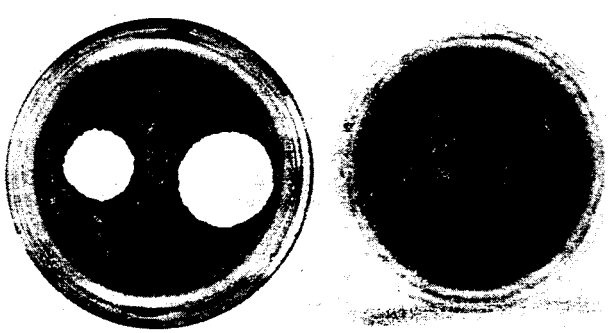

Figure 5. Photograph of base (**left**) and diaphragmatic surface (**right**) of left ventricular bypass pump after disassembly after its application in a patient (Case 3) for 10 days. Note the glistening, firmly adherent fibrinous surface intimately attached to Dacron velour lining and the complete absence of thrombi.

Illustrative Cases

Case 1: The heart-lung machine alone provided adequate circulatory assistance to the failing heart in 1 patient who had had severe aortic valvular disease with preoperative signs of left ventricular failure and a left atrial pressure of 45 mm Hg. After the aortic valve had been replaced with use of cardiopulmonary bypass, an attempt was made to discontinue use of the heart-lung machine, but the left atrial pressure began to rise and the arterial systemic pressure to fall (Fig. 6). As soon as extracorporeal circulation was resumed, left atrial pressure fell to 10 mm Hg, but 15 minutes later, when another attempt was made to discontinue bypass, left atrial pressure again rose to 55 mm Hg and arterial pressure dropped. This time cardiopulmonary bypass was resumed at 3,000 ml/min, and again left atrial pressure fell. This experience led to the decision to prolong assisted circulation in the hope that the heart might recover sufficiently to maintain adequate function. For the next hour and a half, therefore, the bypass flow was gradually reduced until use of the machine was discontinued completely, at which time cardiac output proved adequate.

Other patients, however, have required more prolonged circulatory assistance than the heart-lung machine can provide, and it is in these patients that the left ventricular bypass pump has been applied.

Case 2: A 16 year old girl who had had rheumatic heart disease since the age of 6 years and was in severe cardiac failure at the time of admission. At age 15 she had had mitral valvuloplasty complicated by postoperative episodes of atrial flutter and temporary conversion. About a year before ad-

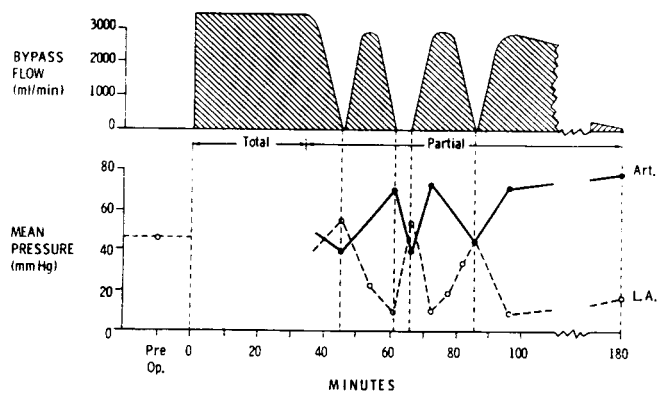

Figure 6. Case 1. Effect of use of heart-lung machine for circulatory assistance after aortic valvular replacement. When an attempt was made at the end of the operation to discontinue use of extracorporeal circulation, left atrial pressure rose, but when partial cardiopulmonary bypass was resumed, it fell to 10 mm Hg. When another attempt was made 15 minutes later to discontinue the bypass, left atrial pressure rose to 55 mm Hg, but promptly fell again when bypass was resumed at a flow of 3,000 ml/min. Left atrial pressure rose once more on a third attempt to discontinue the bypass; this time bypass was resumed at 3,000 ml/min, and this rate was gradually decreased for the next 90 minutes with no rise in left atrial pressure. It was then possible to discontinue cardiopulmonary bypass completely.

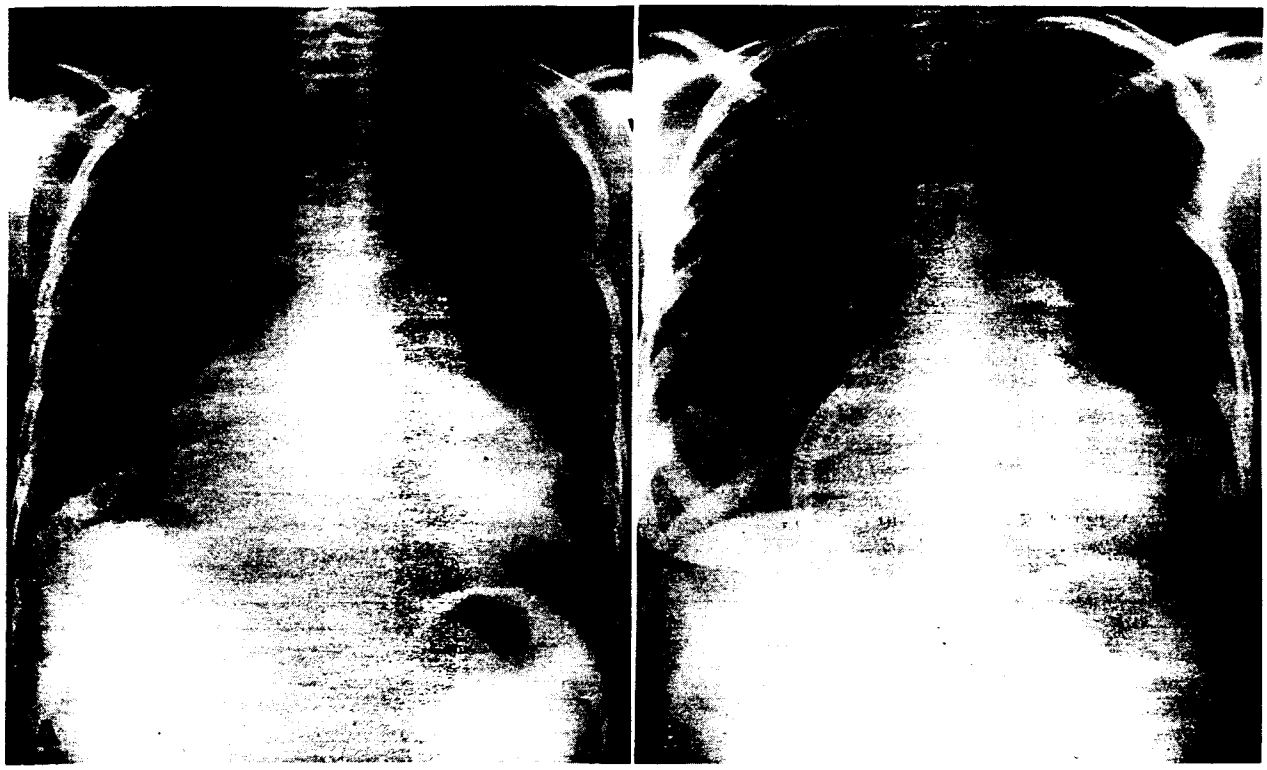

Figure 7. Case 2. Roentgenograms of the chest of a patient critically ill with long-standing rheumatic heart disease and mitral insufficiency. **A,** preoperative roentgenogram showing severe enlargement of the heart. **B,** roentgenogram 6 months after replacement of mitral valve and use of the left ventricular bypass pump. Note reduction in cardiac size.

mission she had had an embolic episode with residual right hemiparesis, and 5 months before admission she had been hospitalized for severe cardiac failure. For 3 months she was treated with 24 million units of penicillin daily, and she had remained at hospital bed rest, receiving maintenance dosages of digoxin (Lanoxin®) and furosemide (Lasix®) daily until her transfer here.

The patient appeared thin and chronically ill, with manifestations of severe mitral insufficiency. Preoperative left atrial pressure was 45 mm Hg. The clinical observations were confirmed by a roentgenogram of the chest, which showed severe enlargement of the left atrium and both ventricles and bilateral pulmonary congestion (Fig. 7A). Cardiac catheterization confirmed the diagnosis of severe mitral insufficiency and indicated the need for replacement of the mitral valve. Because of the high surgical risk in this critically ill patient, preparation was made for possible use of the left ventricular bypass pump.

Operation was performed on October 26, 1967. Through an incision in the right axilla, the outflow connector of the pump was attached to the right axillary artery by end to side anastomosis (Fig. 8). Through a right anterior incision in the fourth intercostal space, the venae cavae were encircled with control tapes. The atria appeared grossly enlarged. After exposure of the right common femoral artery, a plastic catheter was inserted into it for arterial return from the pump oxygenator. The superior and inferior venae cavae were cannulated through the right atrium for venous drainage to the pump oxygenator. Total cardiopulmonary bypass was begun with use of a disposable plastic oxygenator primed with 5 percent dextrose in distilled water under normothermic conditions. Through a longitudinal incision in the left atrium, the incompetent mitral valve was excised and replaced with a small DeBakey mitral valve prosthesis. The atriotomy was then partly closed with a continuous suture, a small opening of about 1 cm being left.

A special Silastic tube (Dow-Corning Corp), with a Dacron velour lining and Dacron velour external surface, for later connection with the left ventricular bypass pump was next attached by suture anastomosis to the opening remaining in the left atrium (Fig. 8a). The connector was passed through a stab wound in the right fifth intercostal space. A smaller tube attached near the proximal end was used to monitor left atrial pressure. Caval tourniquets were loosened, to allow cardiac function to resume with only partial cardiopulmonary bypass. During the next 20 minutes, the left atrial pressure dropped to 25 mm Hg, and partial bypass was gradually reduced until it was discontinued. Within 5 minutes, however, left atrial pressure rose to 35 mm Hg, and mean arterial pressure fell from 80 to 50 mm Hg. Ten minutes after partial cardiopulmonary bypass was resumed at 2,500 ml/min, left atrial pressure fell to 30 mm Hg, and mean arterial pressure rose to 70 mm Hg. With gradual reduction of partial bypass to 800 ml/min, left atrial pressure began to rise again and arterial pressure to fall. More prolonged assisted circulation with the left ventricular bypass pump was therefore deemed necessary.

The air tube from the external power source was connected to the left ventricular bypass pump, and

the atrial and arterial connectors were secured to the pump with Nylon® bands (Fig. 8c). The air-energized pump was slowly actuated. As partial cardiopulmonary bypass was gradually reduced during the next 30 minutes, the flow rate of the left ventricular bypass pump was increased to 1,200 ml/min (Fig. 9). At this point cardiac function seemed to be satisfactory; mean arterial pressure was being maintained at 90 mm Hg,

Figure 8. Diagram showing technique of connecting left ventricular bypass pump after replacement of the mitral valve. **a,** a Dacron velour tube is sutured to the left atrium after closure of the left atrial suture line and is passed through the intercostal space. **b,** a second Dacron velour tube is anastomosed to the axillary artery, and connections are made with the pump. **c,** the gas line is secured, the pump is primed, and the diaphragm is slowly actuated by manual control.

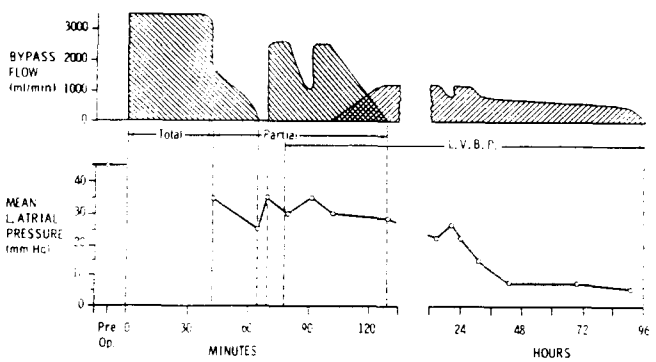

Figure 9. Case 2. Effect of left ventricular bypass pump on left atrial pressure after replacement of mitral valve in patient whose roentgenograms are shown in Figure 7. When an attempt was made to discontinue cardiopulmonary bypass, left atrial pressure rose from 25 to 35 mm Hg. Resumption of partial bypass at 2,500 ml/min was followed by a fall in left atrial pressure. The left ventricular bypass pump was then applied, and at a flow rate of 1,200 ml/min it was possible to discontinue cardiopulmonary bypass. When the pump output was gradually decreased from 1,200 to 800 ml/min 15 hours after operation, left atrial pressure rose from 22 to 26 mm Hg, but when the pump output was again increased to 1,200 ml/min, left atrial pressure promptly fell. The flow rate was gradually reduced without increase in left atrial pressure and with good cardiac output. On the fourth postoperative day, therefore, after the pump was discontinued for 6 hours, it was possible to remove it.

central venous pressure at 20 mm Hg, and left atrial pressure at 28 mm Hg. Cardiopulmonary bypass was discontinued, and the vena caval and femoral arterial cannulas were removed. Protamine was used to restore normal blood coagulation, and all incisions were closed.

Fifteen hours after the operation, the pump output was gradually reduced to 800 ml/min, during

Figure 10. Case 3. Roentgenograms of the chest of patient with severe rheumatic heart disease, causing aortic insufficiency and mitral stenosis. **A,** preoperative roentgenogram. The heart was greatly enlarged. **B,** roentgenogram 18 months after replacement of aortic and mitral valves; the left ventricular bypass pump had been used for 10 days. The heart is notably smaller.

which time left atrial pressure slowly rose from 22 to 26 mm Hg. With an increase in pump output to 1,200 ml/min, left atrial pressure promptly fell. Twenty-seven hours after operation pump output was again slowly reduced to 800 ml/min, and this time left atrial pressure remained stable at 15 mm Hg. By the morning of the third day after operation, when pump flow rate had gradually been reduced to 600 ml/min, left atrial pressure remained stable at 7 mm Hg. Further reduction in pump output did not cause any increase in left atrial pressure.

On the fourth day after operation, use of the pump was discontinued for 6 hours, and since no increase was observed in left atrial pressure, the pump was removed. Inlet and outlet connectors were clamped and cut, and the adjacent region was infiltrated with a local anesthetic. The atrial connector was clamped below skin level, after which it was trimmed and its end oversewn. The arterial connector was similarly trimmed and oversewn. Wound edges were reapproximated with interrupted sutures.

The bypass pump was disassembled and the diaphragm removed to permit inspection of the fibrinous lining of the pumping chamber, which showed a smooth, glistening, autologous lining tenaciously adherent to the Dacron velour lining. No thrombi were seen. The special Dacron velour lining of the inflow and outflow connectors had a similar smooth autologous tissue interface.

Six months after operation, a roentgenogram of the chest showed notable reduction in cardiac size by comparison with the preoperative film (Fig. 7B). The patient recovered completely and has resumed normal life.

The following case illustrates the need for even more prolonged circulatory assistance by the left ventricular bypass pump.

Case 3: A 37 year old woman had entered the hospital because of easy fatigability and severe dyspnea on slight exertion. She had had rheumatic heart disease since the age of 18 years and had had closed mitral valvulotomy at the age of 25. Her symptoms had worsened during the 5 years preceding this hospitalization.

She was thin and appeared to be critically ill, with manifestations of severe aortic insufficiency and mitral stenosis. Chest roentgenogram confirmed the clinical observations of severe enlargement of all 4 chambers of the heart (Fig. 10A). Cardiac catheterization which showed a mean pulmonary arterial pressure of 50 mm Hg, pulmonary wedge pressure of 40 mm Hg and fixed cardiac output of 1.8 liters/min confirmed the diagnosis of severe mitral insufficiency and aortic regurgitation and the need for replacement of aortic and mitral valves. Preparation was made for possible use of the left ventricular bypass pump because the surgical risk in this patient was so high.

Operation was performed on August 8, 1966. The pump was attached as previously described. Through a median sternotomy, the pericardium was opened longitudinally, and numerous adhesions between the heart and pericardium were divided. Both atria appeared extremely enlarged. A pressure needle placed in the left atrium showed the level of left atrial pressure to be extremely elevated at 45 mm Hg. Cannulation was performed, and total cardiopulmonary bypass was begun with use of a disposable plastic oxygenator.

The coronary ostia were cannulated, and the diseased aortic valve was excised. Through an incision in the left atrium, the diseased mitral valve was also excised and was replaced with a no. 3 Starr-Edwards ball valve. The atriotomy was closed with a continuous suture except for an opening of about 1 cm. A special Dacron velour-lined tube for later connection with the left ventricular bypass pump was attached by end to side anastomosis to the opening remaining in the left atrium.

The previously excised aortic valve was replaced with a no. 2 Magovern ball valve. The coronary perfusion catheters were removed just before closure of the aortotomy was completed. Caval tourniquets were then loosened to allow cardiac function to resume with use of partial cardiopulmonary bypass. Fifteen minutes later, direct measurement of left atrial pressure was 35 mm Hg, with left ventricular end-diastolic pressure of 20 mm Hg.

The special Dacron atrial connector was brought out through a stab wound in the right fourth intercostal space. The atrial and arterial connectors were attached to the left ventricular bypass pump (Fig. 8). The air tube from the external power source was connected, and the air-energized pump was slowly actuated.

As partial cardiopulmonary bypass was gradually decreased during the next 10 minutes, the flow rate of the left ventricular bypass pump was increased to about 1,200 ml/min. At this point, cardiac function appeared to be satisfactory; blood pressure was about 120/80 mm Hg, central venous pressure about 12 mm Hg, left atrial pressure 15 mm Hg, and pulmonary systolic arterial pressure 40 mm Hg. Use of cardiopulmonary bypass was therefore discontinued, and vena caval and femoral arterial cannulas were removed. Protamine was used to restore normal blood coagulation, and all incisions were closed.

On the third day after operation, the patient was doing satisfactorily with the pump output reduced to about 800 ml/min. The electrocardiogram and systemic, arterial, left atrial, pulmonary arterial and central venous pressure were monitored. The effect of use of the bypass pump on left atrial pressure is shown in Figure 11. A reduction in pump output resulted in an increase in left atrial pressure. With reestablishment of a pump flow of about 1,000 ml/min, left atrial pressure promptly decreased. By the morning of the fourth day after operation, the pump flow rate had been gradually reduced to 400 ml/min. At noon on that day, however, there was a progressive decrease in systemic blood pressure and a moderate increase in left atrial pressure associated with decreased urinary output to about 10 ml/30 min. Administration of 1 ml of meralluride (Mercuhydrin®) and 50 mg of hydrochlorothiazide (Hydrodiuril®) yielded no response within 5 hours. The output of the left ventricular bypass pump was then increased from 400 to 800 ml/min, with immediate diuresis and restoration of left atrial pressure to normal (Fig. 12).

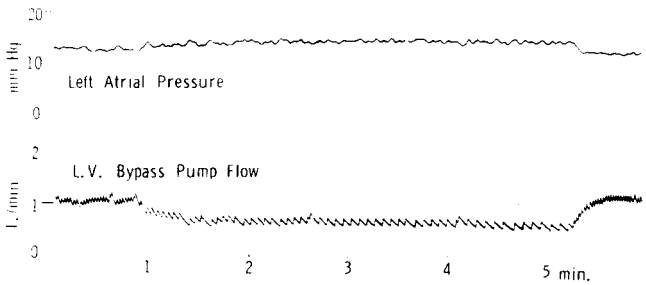

Figure 11. Case 3. Effect of left ventricular bypass pump on left atrial pressure. As the pump flow is decreased, left atrial pressure rises; as flow is increased, left atrial pressure falls.

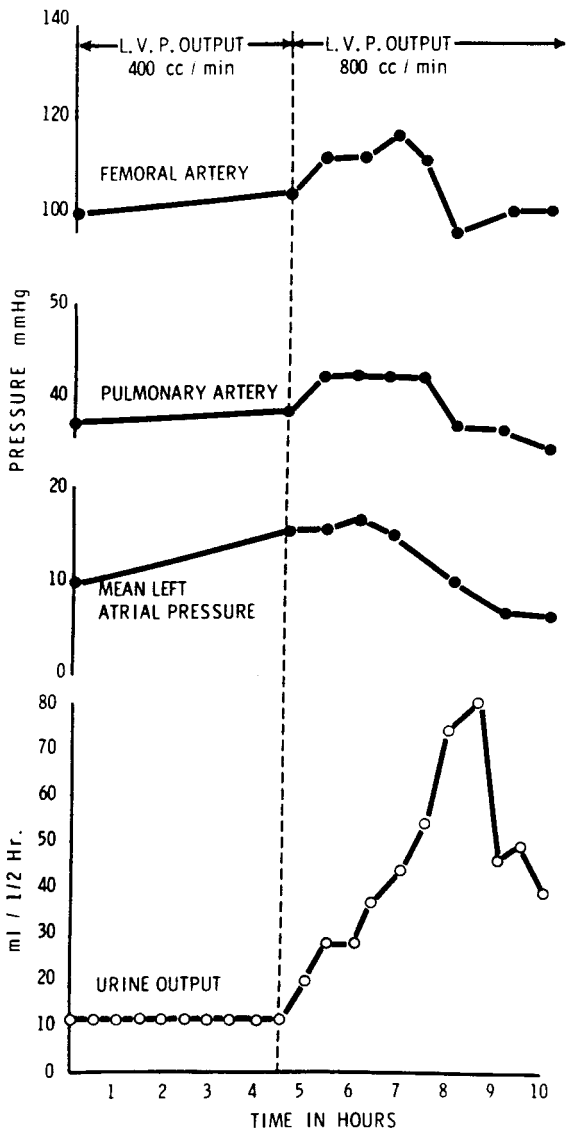

Figure 12. Case 3. Clinical data during left ventricular bypass pumping. When, on the fourth day after operation, systemic blood pressure continued to fall while left atrial pressure rose moderately and urinary output decreased to about 10 ml/30 min, administration of Mercuhydrin® and Hydrodiuril® failed to produce any response within 5 hours. As soon as the output of the left ventricular bypass pump (L.V.P.) was increased from 400 to 800 ml/min, however, diuresis began, and left atrial pressure became normal.

On the seventh day after operation, after infusion of 500 ml of saline solution during renal function studies, left atrial pressure slowly rose during a 6 hour interval. Rales could be heard in the chest, the patient began to cough pink, frothy sputum and became increasingly dyspneic, and acute pulmonary edema rapidly ensued. Left atrial pressure rose sharply to 45 mm Hg, at which point the outflow of the left ventricular bypass pump was increased from 450 to 1,400 ml/min (Fig. 13). Within minutes, left atrial pressure dropped rapidly to about 15 mm Hg concomitantly with disappearance of all signs of acute pulmonary edema.

On the ninth day after operation, with continued improvement of the patient's condition, the outflow of the pump was reduced to 350 ml/min, and the patient was able to get out of bed (Fig. 3). A roentgenogram of the chest at that time showed the lung fields to be clear and the cardiac silhouette to be somewhat smaller. Continued reduction in output of the pump caused no rise in left atrial pressure, and on the tenth postoperative day use of the pump was discontinued for 6 hours. Since no increase in left atrial pressure was observed, it was decided to remove the pump.

After disassembly of the bypass pump, the diaphragm was removed for inspection of the lining of the pumping chamber. The tenacity of the smooth, glistening autologous lining can be seen in Figure 5; no thrombi had formed. The special Dacron velour lining of the inflow and outflow connectors also showed a smooth autologous tissue interface.

The patient was discharged on the twenty-ninth day after operation and later returned to work and resumed normal activity. She was seen 6 months later and was completely symptom-free. Cardiac catheterization at that time showed restoration of cardiac function to relatively normal levels. The low cardiac output of 1.8 liter/min before operation increased to 3 liters/min after operation, and hemodynamic studies showed that the mean wedge pressure of 40 mm Hg before operation fell to 20 mm Hg.

Roentgenogram of the chest 18 months after operation showed significant reduction in cardiac size by comparison with preoperative films (Fig. 10B). The patient has since remained asymptomatic.

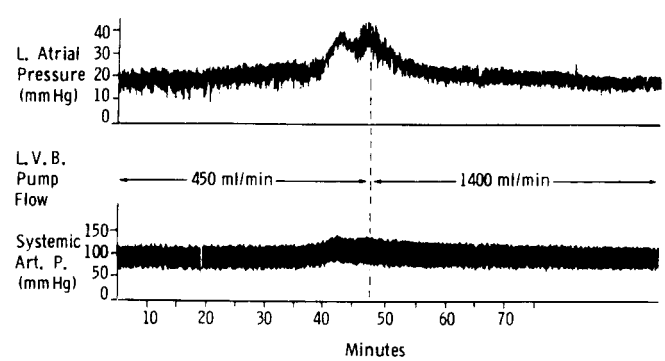

Figure 13. Case 3. Effect of use of left ventricular bypass pump on acute left ventricular failure. When, on the seventh day after aortic and mitral valve replacement signs of acute pulmonary edema appeared, left atrial pressure rose sharply to 45 mm Hg. An increase in outflow of the pump from 450 to 1,400 ml/min caused left atrial pressure to fall promptly to 15 mm Hg, with disappearance of all signs of acute pulmonary edema.

Discussion

Evidence from both experimental and clinical experience adds support to the hypothesis that the left ventricular bypass pump, by reducing left atrial pressure and therefore left ventricular end-diastolic pressure, reduces left ventricular strain, relieves pulmonary congestion and increases arterial oxygen tension. Improvement in cardiac output, with increase in coronary perfusion, thus enhances myocardial recuperation. By providing systemic organ perfusion, as illustrated by improvement in renal function and dramatic relief of both pulmonary edema and heart failure, it allows the heart to recuperate adequately to maintain satisfactory cardiac output for survival. Moreover, this particular pump permits perfusion of as much as 2 to 3 liters/min without significant damage to the blood, since plasma hemoglobin was maintained within acceptable levels in the patients in whom it was tried. Indeed, in the second patient, plasma hemoglobin level was progressively reduced during the 10 days when the pump was used from about 33.6 mg/100 ml on the first day after operation to about 4.8 mg/100 ml on the tenth day. This low level of plasma hemoglobin indicates that the fibrinous surface that develops on the Dacron velour lining of the pump is compatible for blood flow.

Problems in clinical application: The effective use of this pump in patients who require cardiac assistance does not have wide clinical application for a number of reasons: For one thing, the cost of using it clinically is almost prohibitive. For another, its clinical application necessitates a major operation, with thoracotomy. In the patients in whom it has been used, major operation and thoracotomy were essential for correction of valvular heart disease, but most patients who need cardiac assistance are suffering from severe coronary arterial disease and in them such a major operation increases the risk. The left ventricular bypass pump, in its present stage of development, must therefore remain an investigative procedure.

For cardiac assistance for several days or weeks, the Dacron velour has proved satisfactory as a blood interface, producing minimal and tolerable damage to the blood. For longer or indefinite periods, however, it is not satisfactory because the fibrinous material deposited on the lining continues to build up and ultimately will impede mechanical effectiveness of the pump and outflow tract. Mechanical assistance for long-term support or possible total replacement of the biologic heart therefore remains unachieved insofar as a satisfactory blood interface is concerned. The blood interface is perhaps the most critical problem yet to be solved in the development of an artificial heart.

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